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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,680	06/07/2001	Wade Blair	3053-4087	8187

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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/876,680

Applicant(s)

BLAIR ET AL.

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This action is in response to paper filed 28 September 2005.

Claims 1- 23 are pending.

#### ***Claim Objections Withdrawn***

Claims 12 and 23 are objected to because of the following informalities: The claims refer to a method and the claim that it depends from is not a method. It appears that they are intended to depend from claims 11 and 22, respectively, and will be treated as such.

Applicant has amended the claims and the objection is withdrawn.

#### ***Rejections Withdrawn***

#### ***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-23 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 13 recite the limitation "high-

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volume". This limitation is not apparent in the specification. The specification recites "high throughput" in several places (see for example page 1, line 26).

Applicant has amended the claims and the rejection is withdrawn.

***Claim Rejections - 35 USC § 102***

Claims 1, 4, and 10 were rejected under 35 U.S.C. 102(b) as being anticipated by Chen *et al.* (from IDS, 1994 Journal of Virology Vol. 68, pages 654-660).

Applicants arguments are persuasive and the rejection is withdrawn.

Claims 1, 4, 10, and 11 were rejected under 35 U.S.C. 102(b) as being anticipated by Haseltine *et al.*

Applicants arguments are persuasive and the rejection is withdrawn.

***Claim Rejections - 35 USC § 103***

Claims 1, 5-9, and 15-21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Chen *et al.* (1996, from IDS), and further in view of Gibbs *et al.* (from IDS, cited in previous action), Shi *et al.* (cited in previous action), Collman *et al.* (cited in previous action), or Li *et al.* (cited in previous action).

Applicants arguments are persuasive and the rejection is withdrawn.

Claims 1-3, 11-14, 22, and 23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al., Haseltine et al. and Liu et al.

Applicants arguments are persuasive and the rejection is withdrawn.

### **NEW REJECTIONS**

#### ***Claim Rejections - 35 USC § 103***

Claims 1-4, 10, 11, 13-15, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terwilliger *et al.* and Liu *et al.* (previously cited)

The claims are drawn to replication competent HIV-1 viral vector in which a non-essential region for viral replication has been replaced by a reporter gene. The further limitation "suitable for use" is an **intended use limitation** and without specific structural limitations in the claims, this limitation does not carry any weight in terms of patentability. The method claims only require contacting cells with a test compound that are infected or will be infected and comparing that to a control.

Terwilliger *et al.* teach the invention essentially as claimed. Terwilliger *et al.* teach a replication competent HIV clone with a deletion in a non-essential region of the genome, a reporter gene, and a method to screen antiviral compounds (abstract, Figure 1 and Figure 5).

Terwilliger *et al.* do not teach SEAP or luciferase or a mutated luciferase.

Liu *et al.* teach that secreted reporter proteins offer distinct advantages and benefits over other reporter genes because of ease of monitoring and ability to sample over time (Introduction, page 153).

One of ordinary skill in the art at the time of invention it would have been motivated to modify the vector of Terwilliger *et al.* with the improved luciferase reporter gene (Terwilliger *et al.* uses CAT) to gain the advantages as taught by Liu *et al.* At the time of invention it would have been obvious to use the modified virus in the assay of Terwilliger *et al.* (as discussed above) for the benefit of ease of screening of compounds that could be used as antivirals.

Thus, it would have been *prima facie* obvious to modify the virus of Terwilliger *et al.* with the reporter gene of Liu *et al.* with the expectation of success of having a virus that is easier to use for screening antiviral compounds.

Claim 1-3, 5-9, 11-13, 15-19, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terwilliger *et al.* and Liu *et al.* as applied to claims 1-4, 10, 11, 13-15, 21, and 22 above, and further in view of Gibbs *et al.* (from IDS, cited in previous action) or Shi *et al.* (cited in previous action) or Collman *et al.* (cited in previous action), or Li *et al.* (cited in previous action).

Terwilliger *et al.* and Liu *et al.* teach a replication competent HIV-1 viral vector in which *nef*, a non-essential region for viral replication, has been replaced by a secreted reporter gene and method of screening antiviral compounds as discussed above.

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Terwilliger *et al.* and Liu *et al.* do not teach that the vpr region is non-essential or the other viral clones.

Gibbs *et al.* teach a proviral clone pNL4-3 and that vpr is a non essential region and can be deleted, figures 2 and 3 and Discussion.

Shi *et al.* teach a similar viral vector using the proviral clone HIV-I Lai.

Collman *et al.* teach an infectious clone of HIV-1, p89.6 which has a novel tropism.

Li *et al.* teach an infectious proviral clone of pYU-2.

Each of the references teaches an infectious HIV-1 clone. One of ordinary skill in the art at the time of invention would have known that the assay of Terwilliger *et al.* and Liu *et al.* could be used with other proviral clones to study other clones ability to infect cells or their tropism.

One of ordinary skill in the art at the time of invention would have known that the choice of cells would include those that can be infected by the virus or made to be infected because macrophage-tropic/non-syncytium-inducing (NSI) viruses use CCR5 as a receptor for cell entry.

It would have been *prima facie* obvious to one skilled in the art to modify the virus of Terwilliger *et al.* and Liu *et al.* with other infectious proviral clones or appropriate cell lines to study infection of different HIV-1 clones with the expectation of success.

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**Conclusion**


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Myron G. Hill  
Patent Examiner  
December 1, 2005

  
JAMES HOUSEL 12/12/05  
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